

**REMARKS/ARGUMENTS**

Claims 35, 37-42, 44-55, and 57 remain in this application. Claims 36, 43, 56, 58, and 59 have been cancelled. Claims 35, 41, 48, and 51 are currently being amended.

Applicants thank the examiner for the interview on January 6, 2004, for her helpful comments and suggestions, and for her thoughtful consideration of the present application. The current amendments to the claims were discussed at the interview and made at the examiner's direction to advance prosecution.

Claims 35-59 stand rejected under 35 U.S.C. § 112, first paragraph. The examiner alleges that the term "single layer core matrix" does not find written support in the application because the term is not explicitly used in the application, despite the fact that a single layer core matrix is shown in Example 2. As discussed in the interview, applicants respectfully disagree that explicit language is required for § 112 purposes. However, "single layer" has been deleted at the examiner's request. Accordingly, applicants believe that the § 112 rejection is moot.

Claims 35-38, 40-48, 50-53, and 55-59 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,366,738 (Rork et al.) in view of U.S. Patent No. 6,589,994 to Artman et al. (Artman). Claims 39, 49, and 54 stand rejected under 35 U.S.C. § 103(a) further in view of U.S. Patent No. 5,415,871 (Pankhania et al.).

The examiner stated during the interview that the rejection with respect to Artman would be removed if the Applicant makes a statement that the application and Artman are commonly owned. The Applicants hereby state that the present application and Artman were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person, namely, NPS Pharmaceuticals, Inc.

Moreover, Applicants believe that the following agreement was reached with the examiner reached regarding the differences between the presently claimed invention, Rork, and Artman, namely:

(a) Rork teaches a particular sustained-release formulation having an impermeable, insoluble coating containing apertures through which the active compound is released from the core. While Rork presents a broad "laundry list" of active ingredients that may be adapted for use in the Rork formulation, Rork does not specifically teach or suggest that the compounds in the presently claimed formulation be adapted for such use.

(b) Artman discloses isovaleramide and related compounds but also does not teach or suggest their use in a sustained-release formulation. Rather, Artman teaches only that such compounds could be taken orally "1-2 at a time for a maximum of four times per day" (col. 15, lines 38-39).

(c) Neither Rork nor Artman teach or suggest that isovaleramide or other compounds in the claimed formulation have short half-lives and thus that a sustained release formulation would be necessary where extended release is desirable such as for example the treatment of convulsions or spasticity. Rather it is the present application that teaches the pharmokinetics of the compounds and thus the desirability of and motivation for manufacturing the presently claimed sustained-release formulation.

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if necessary to advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a

check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date 3/1/04

By S. A. Bent

FOLEY & LARDNER  
Washington Harbour  
3000 K Street, N.W., Suite 500  
Washington, D.C. 20007-5143  
Telephone: (202) 672-5404  
Facsimile: (202) 672-5399

Stephen A. Bent  
Attorney for Applicant  
Registration No. 29,768